

Article 3.5 Reporting of Human Immunodeficiency Virus (HIV) Infection

Sub-Article 1. Definitions

(1) Adopt Section 2641.5 as follows:

Section 2641.5 Alternative Testing Site.

“Alternative Testing Site” means an anonymous HIV testing site funded by the California Department of Health Services, administered by a county health department and operated pursuant to Health and Safety Code, Sections 120890-120895.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(2) Adopt Section 2641.10 as follows:

Section 2641.10. Anonymous Counseling and Testing Program.

“Anonymous Counseling and Testing Program” means a program offering HIV counseling and testing while maintaining anonymity of the patient.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(3) Adopt Section 2641.15. as follows:

Section 2641.15. Anonymous HIV Test.

“Anonymous HIV Test” means an HIV test that maintains the anonymity of the patient.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety  
Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and  
Safety Code.

(4) Adopt Section 2641.20 as follows:

Section 2641.20. Biological Specimen.

“Biological specimen” means any material that is derived from the human body.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Section 1206, Business and Professions Code; Sections 100180, 101160, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(5) Adopt Section 2641.25 as follows:

Section 2641.25. Confidential HIV Test.

“Confidential HIV Test” means an HIV test that links the test results to the patient in a restricted manner to protect against unauthorized disclosure of the identity of the patient.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775 and 121025, Health and Safety Code.

(6) Adopt Section 2641.30 as follows:

Section 2641.30. Confirmed HIV Test.

“Confirmed HIV test” means:

- (a) a procedure which verifies the presence of HIV infection as determined by any clinical laboratory test or examination used to detect the presence of HIV, a component of HIV, or antibodies to or antigens of HIV, including the HIV antibody (HIV-Ab), HIV p-24 antigen, Western blot (Wb), and immunofluorescence antibody tests; or
- (b) for the purpose of this Article, all tests used to monitor HIV infection, including HIV nucleic acid detection.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1241, 1265 and 1281, Business and Professions Code; Sections 100180, 101150, 101160, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(7) Adopt Section 2641.35 as follows:

Section 2641.35. Department.

“Department” means the California Department of Health Services, Office of AIDS.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(8) Adopt Section 2641.45 as follows:

Section 2641.45. Health Care Provider.

“Health care provider” means an individual who submits a biological specimen to a laboratory for a test to detect the presence of HIV, a component of HIV or antibodies to or antigens of HIV, receives the test results and is;

(a) licensed under the provisions of Business and Professions Code, Division 2 (Healing Arts) and acting within his or her scope of practice, or;

(b) a designee of a physician and surgeon acting under the general supervision of that physician or surgeon, or;

(c) a person working in a publicly-funded confidential counseling and testing program acting under the general supervision of, and following the protocols approved by, the local Health Officer for the local health department.

Authority cited: Sections 100180, 100275, 101160, 120125 and 120130, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1241, 1281 and 1285, Business and Professions Code; Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.



(9) Adopt Section 2641.50 as follows:

Section 2641.50. Health Officer and Local Health Officer.

“Health Officer and Local Health Officer” means the officer appointed by the local governing body (county, city, and district), as defined in Section 2500.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(10) Adopt Section 2641.55 as follows:

Section 2641.55. HIV/AIDS Case Report.

“HIV/AIDS Case Report” means California Department of Health Services HIV/AIDS Confidential Case Report form, Adult (DHS 8641A (9/01) or Pediatric (DHS 8641P (9/01), hereby incorporated by reference in this Article and available from the local health department or the Department.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(11) Adopt Section 2641.60 as follows:

Section 2641.60. Laboratory.

“Laboratory” means a ‘clinical laboratory,’ a ‘physician office laboratory,’ or a ‘public health laboratory,’ as defined in Business and Professions Code, Section 1206, that is authorized to perform clinical laboratory tests or examinations in California, or a clinical laboratory located outside of the State of California that is licensed pursuant to Business and Professions Code Section 1241(a) and that tests specimens originating in California.

Authority cited: Sections 1224 and 1288, Business and Professions Code; Sections 100180, 100275, 101160, 120125 and 120130, Health and Safety Code.

Reference: Sections 1206, 1241, 1220, 1265 and 1281, Business and Professions Code.

(12) Adopt Section 2641.65 as follows:

Section 2641.65. Laboratory Test.

"Laboratory test" means a clinical laboratory test or examination as defined in Business and Professions Code, Section 1206 (a) (4) and performed by a laboratory as defined in this Article.

Authority: Sections 1224 and 1288, Business and Professions Code; Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 1202.5 and 1206, Business and Professions Code; Section 101160, Health and Safety Code.

(13) Adopt Section 2641.70 as follows:

Section 2641.70. Local Health Department.

“Local health department” means the governing body providing public health services to cities and/or counties, as identified in Health and Safety Code, Section 101185.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(14) Adopt Section 2641.75 as follows:

Section 2641.75. Non-Name Code.

“Non-Name Code” means a designation required by Section 2643.5 of this Article, that does not readily identify an HIV-infected individual. Components of the Non-Name Code shall be listed in the following order, and shall consist of an individual’s:

- (a) Soundex code;
- (b) complete date of birth (2-digit month, 2-digit day, 4-digit year);
- (c) gender (male [1], female [2], transgender male-to-female [3], or transgender female-to-male [4]); and
- (d) last four digits of the Social Security Number (if not available, use four digits of zero).

Authority cited: Sections 100180, 100275, 120125, 120130 and 120140, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(15) Adopt Section 2641.77 as follows

Section 2641.77 Partial Non-Name Code

A Partial Non-Name Code means a designation required by Section 2643.10 of this Article, that does not readily identify the HIV-infected individual. Components of the Partial Non-Name Code shall be listed in the following order, and shall consist of an individual's:

- (a) Soundex code;
- (b) complete date of birth (2-digit month, 2-digit day, 4-digit year) and;
- (c) gender (male [1], female [2], transgender male-to-female [3], or transgender female-to-male [4]).

Authority cited: Sections 100180, 100275, 120125, 120130 and 120140 Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(16) Adopt Section 2641.80 as follows:

Section 2641.80. Personal Information.

“Personal information” means an individual’s complete Social Security Number, complete name or surname, home address, California driver’s license or identification number, electronic mail address or telephone number.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.



(17) Adopt Section 2641.85 as follows:

Section 2641.85. Publicly-Funded Confidential Counseling and Testing Program.

“Publicly-funded Confidential Counseling and Testing Program” means a program financed by federal, state or local governmental agencies that provides confidential HIV tests to patients.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(18) Adopt Section 2641.90 as follows:

Section 2641.90. Soundex Code.

“Soundex code” means a phonetic, alphanumerical formula which is used to convert the first letter and sequential consonants of an individual’s surname into an algorithm. The Soundex code instructions are identified by the Department as form DHS 8641 SC (9/01), hereby incorporated by reference in this Article.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

Sub-Article 4. Reporting Requirements

(19) Adopt Section 2643.5 as follows:

Section 2643.5. HIV Reporting by Health Care Providers.

(a) Each health care provider that orders a laboratory test used to identify HIV, a component of HIV, or antibodies to or antigens of HIV shall submit the following to the laboratory performing the test:

(1) A pre-printed laboratory requisition form which includes all documentation as specified in 42 CFR 493.1105 (57 FR 7162, Feb. 28, 1992, as amended at 58 FR 5229, Jan. 19, 1993) and adopted in Business and Professions Code, Section 1220, or;

(2) A completed Department of Health Services Counseling and Testing Program Confidential HIV Antibody Test laboratory requisition form, DHS 8257C (1/02), hereby incorporated by reference in this Article.

(b) The person authorized to order the laboratory test shall include the following when submitting information to the laboratory:

(1) Patient surname; and

(2) Patient date of birth (2-digit month, 2-digit day, 4-digit year); and

(3) Patient gender (male, female, transgender male-to-female, or transgender female-to-male); and

(4) Date biological specimen was collected; and

(5) Name, address, telephone number of the health care provider and the facility where services were rendered, if different.

(c) Each health care provider shall, within seven calendar days of receipt of a patient's confirmed HIV test and Partial Non-Name Code from a laboratory, complete the Non-Name Code (as specified in Section 2641.75) and report the confirmed HIV test to the local Health Officer for the jurisdiction where the health care provider facility is located. The report shall consist of a completed copy of the HIV/AIDS Case Report form.

(d) HIV reporting by Non-Name Code to the local Health Officer, via submission of the HIV/AIDS Case Report, shall not supplant the reporting requirements in Article 1 of this Subchapter when a patient's medical condition progresses from HIV infection to an Acquired Immunodeficiency Syndrome (AIDS) diagnosis.

(e) When reporting a confirmed HIV test, a health care provider shall not report a patient's personal information to the local Health Officer except for patients whose clinical conditions meet the AIDS reporting criteria, as specified in Article 1 of this Subchapter.

(f) A health care provider who receives notification from an out-of-state laboratory of a confirmed HIV test for a California patient shall report the findings to the local Health Officer for the jurisdiction where the health care provider facility is located.

(g) When a health care provider orders multiple HIV-related viral load tests for a patient, or receives multiple laboratory reports of a confirmed HIV test, the health care provider shall be required to submit only one HIV/AIDS Case Report, per patient, to the local Health Officer.

(h) For all HIV-infected patients without an AIDS diagnosis, the health care provider shall maintain a system which cross-references patient data by using either the Partial

Non-Name Code or the Non-Name Code. This system shall be used only to exchange information with the Local Health Officer in order to complete or unduplicate the HIV case reports.

(i) Information reported pursuant to this Article is acquired in confidence and shall not be disclosed by the health care provider except as authorized by this Article, other state or federal law, or with the written consent of the individual to whom the information pertains or the legal representative of that individual.

Authority cited: Sections 100180, 100275, 120125, 120130 and 120140, Health and Safety Code.

Reference: Sections 1202.5, 1206, 1206.5, 1220, 1241, 1265 and 1281, Business and Professions Code; Sections 100180, 101160, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(20) Adopt Section 2643.10 as follows:

Section 2643.10. HIV Reporting by Laboratories.

(a) The laboratory director or authorized designee shall create a Partial Non-Name Code (as specified in Section 2641.77) for each confirmed HIV test.

(b) The laboratory director or authorized designee shall, within seven calendar days of determining a confirmed HIV test, report the confirmed HIV test to the Health Officer of the local health jurisdiction where the health care provider facility is located. The report shall include the:

(1) Partial Non-Name Code of the patient; and

(2) Name, address, and telephone number of the health care provider and the facility that submitted the biological specimen to the laboratory, if different.; and

(3) Name, address, and telephone number of the laboratory; and

(4) Laboratory report number as assigned by the laboratory; and

(4) Laboratory results of the test performed; and

(5) Date the biological specimen was tested in the laboratory.

(c) A laboratory shall not transmit a patient's personal information to the local health department.

(d) A laboratory that receives incomplete patient data from a health care provider for a biological specimen with a confirmed HIV test, shall contact the submitting health care provider to obtain the information required pursuant to Section 2643.5 (b) (1)-(5), prior to reporting the confirmed HIV test to the local Health Officer.

- (e) A laboratory shall convey the patient's Partial Non-Name Code to the submitting health care provider when reporting confirmed HIV test results.
- (f) If a laboratory transfers a biological specimen to another laboratory for testing, the laboratory that first receives the biological specimen from the health care provider shall report confirmed HIV tests to the local Health Officer.
- (g) Laboratories shall not submit reports to the local health department for confirmed HIV tests for patients of an Alternative Testing Site or other anonymous HIV testing program, a blood bank, a plasma center, or for participants of a blinded and/or unlinked seroprevalence study.
- (h) When a California laboratory receives a biological specimen for testing from an out-of-state laboratory or health care provider, the California director of the laboratory shall ensure that a confirmed HIV test is reported to the state health department in the state where the biological specimen originated.
- (i) When a California laboratory receives a report from an out of state laboratory that indicates evidence of a confirmed HIV test for a California patient, the California laboratory shall notify the local Health Officer and health care provider in the same manner as if the findings had been made by the California laboratory.
- (j) Information reported pursuant to this Article is acquired in confidence and shall not be disclosed by the laboratory except as authorized by this Article, other state or federal law, or with the written consent of the individual to whom the information pertains or the legal representative of the individual.

Authority cited: Sections 1224, Business and Professions Code; Sections 100180,

100275, 120125, 120130 and 120140, Health and Safety Code.

Reference: Sections 1206, 1206.5, 1209, 1220, 1241, 1265, 1281 and 1288, Business

and Professions Code; Sections 100180, 101150, 120175, 120775, 120885-120895

and 121025, Health and Safety Code.



(21) Adopt Section 2643.15 as follows:

Section 2643.15 HIV Reporting by Local Health Officers.

(a) The local Health Officer or his or her authorized designee shall match and unduplicate laboratory reports of confirmed HIV tests with the local health department HIV/AIDS registry database and with HIV/AIDS Case Reports received from health care providers and not entered into the database.

(b) The Health Officer or his or her authorized designee shall, within 45 calendar days of receipt of a laboratory report of a confirmed HIV test, submit unduplicated HIV/AIDS Case Reports to the Department.

(1) HIV/AIDS Case Reports shall be sent by courier service, U.S. Postal Service Express or Registered mail, or other traceable mail to the California Department of Health Services, Office of AIDS, HIV/AIDS Case Registry.

(2) The local Health Officer or his or her authorized designee shall not report confirmed HIV tests for patients of an Alternative Testing Site or other anonymous counseling and testing program, a blood bank, a plasma center, or for participants of a blinded and/or unlinked HIV seroprevalence study.

(c) The local Health Officer or his or her authorized designee shall not submit an HIV/AIDS Case Report to the Department for an infant under the age of 18 months, unless the infant's HIV infection is confirmed.

(d) Information reported pursuant to this Article is acquired in confidence and shall not be disclosed by the local Health Officer or his or her authorized designee except as

authorized by this Article, other state or federal law, or with the written consent of the individual to whom the information pertains or the legal representative of the individual.

Authority cited: Sections 100180, 100275, 120125, 120130 and 120140, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.

(22) Adopt Section 2643.20 as follows:

Section 2643.20. HIV Reporting Exemptions.

Alternative Testing Sites; other anonymous or unlinked HIV testing programs; blood banks; plasma centers; and blinded and/or unlinked seroprevalence studies are exempt from these HIV reporting regulations.

Authority cited: Sections 100180, 100275, 120125 and 120130, Health and Safety Code.

Reference: Sections 100180, 120175, 120775, 120885-120895 and 121025, Health and Safety Code.